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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/561,046	12/16/2005	Miyuki Sekine	053673-0027	1908
20277 7590 05/04/2009 MCDERMOTT WILL & EMERY LLP 600 13TH STREET, N.W. WASHINGTON, DC 20005-3096				
EXAMINER DELCOTTO, GREGORY R				
ART UNIT		PAPER NUMBER		
1796				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/561,046

**Applicant(s)**

SEKINE ET AL.

**Examiner**

Gregory R. Del Cotto

**Art Unit**

1796

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on RCE filed 4/20/09.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1, 2 and 4-7 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2 and 4-7 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
- Paper No(s)/Mail Date \_\_\_\_\_

- 4) ☐ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. Claims 1, 2, and 4-7 are pending. Claim 3 has been canceled. Note that, Applicant's arguments and amendments filed 4/20/09 have been entered.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/20/09 has been entered.

#### ***Priority***

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

#### **Objections/Rejections Withdrawn**

The following objections/rejections as set forth in the Office action mailed 12/18/08 have been withdrawn:

None.

#### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, and 4 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino et al (US 4,678,598), Niemiec et al (US 6,495,498), or Wetzel (US 4,885,107), all in view of Watson et al (US 4,136,163).

Ogino et al a liquid shampoo composition containing from 5 to 30% by weight of a surface active agent, from 0.05 to 5% by weight of a skin sensation inducing aromatic chemical such as menthol and camphor, and a modified cyclodextrin. See Abstract. Suitable surfactants include anionic surfactants, etc. See column 3, line 40 to column 4, line 15. The shampoo compositions may also contain any arbitrary ingredients ordinarily incorporated into shampoo compositions such as propylene glycol, glycerine, etc. The remainder of the composition is generally water. See column 6, lines 50-65.

Niemiec et al teach two-in-one detergent compositions comprised of at least one water soluble silicone agent, at least one cationic conditioning agent, and a detergent.

The compositions are useful for use in shampoos, baths and shower gels. See Abstract. Suitable detergents include anionic surfactants such as alkyl sulfates, etc. See column 6, lines 40-69. Additionally, the compositions may include a humectant which is present in an amounts from 0.5 to 10% by weight of the composition and include polyols such as glycerine, propylene glycol, etc. See column 13, Lines 1-30. Analgesics such as menthol may also be used in the compositions in amounts from about 0.001 to about 20% by weight. See column 15, line 20 to column 16, line 25.

Wetzel teaches shampoos which comprise a synthetic surfactant, selenium sulfide, a suspending agent, and water. See Abstract. Suitable surfactants include anionic, amphoteric, nonionic, etc. See column 2, lines 5-15. Additionally, the compositions may contain a variety of optional components suitable for rendering such compositions more acceptable. These components include viscosity modifiers such as propylene glycol, menthol, etc. These optional components are used individually at a level of from about 0.01% to 10% by weight of the composition. See column 6, lines 40-65.

Ogino et al, Niemiec et al, or Wetzel do not teach the use of a N-substituted-p-menthane-3-carboxamide derivative or a composition containing menthol, a N-substituted-p-menthane-3-carboxamide derivative, an anionic surfactant, a polyhydric alcohol, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Watson et al teach N-substituted-p-menthane-3-carboxamides which have the property of stimulating the cold receptors of the nervous system of the human body to

produce a desirable cold sensation and are used for this purpose in a variety of edible and topical preparations. See Abstract. Watson et al also teach that the N-substituted-p-menthane-3-carboxamides provide a cooling sensation without the disadvantages of menthol, which are a very strong odor and high volatility. See column 2, lines 1-15. Suitable consumer products in which they are used include solutions, emulsions, pastes, etc., for shampoos, hair oils, etc. See column 3, lines 15-55. Note that, the Examiner asserts that Watson et al teach N-substituted-p-menthane-3-carboxamides derivatives which are the same as recited by the instant claims. See column 2, lines 27-69 and column 6, lines 40-69. The carboxamides will generally be added to personal care products based on soaps or surfactants in amounts from 0.5 to 4% by weight. See column 8, lines 50-62.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a N-substituted-p-menthane-3-carboxamide derivative in the composition taught by Ogino et al, Niemiec et al, or Wetzal, with a reasonable expectation of success, because Watson et al teach that a N-substituted-p-menthane-3-carboxamide derivative produces a desirable cold sensation in a similar topical cleaning composition.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to formulate a composition containing menthol, a N-substituted-p-menthane-3-carboxamide derivative, an anionic surfactant, a polyhydric alcohol, and the other requisite components of the composition in the specific amounts as recited by the instant claims, with a reasonable expectation of success, because the broad teachings

of Ogino et al, Niemiec et al, or Wetzel in combination with Watson et al suggest a composition containing menthol, a N-substituted-p-menthane-3-carboxamide derivative, an anionic surfactant, a polyhydric alcohol, and the other requisite components of the composition in the specific amounts as recited by the instant claims.

Note that, essentially, the prior art teaches the equivalence of menthol to N-substituted-p-menthane-3-carboxamide derivatives as cold sensation agents in personal cleansing compositions; it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See MPEP 2144.06.

Claims 5-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ogino et al (US 4,678,598), Niemiec et al (US 6,495,498), or Wetzel (US 4,885,107), all in view of Watson et al (US 4,136,163 as applied to claims 1, 2, and 4 above, and further in view of Shiroyama et al (US 6,328,982).

Ogino et al, Niemiec et al, Wetzel, and Watson et al are relied upon as set forth above. However, none of the references teach the use of compounds such as p-menthane-3,8-diol and vanillyl butyl ether in addition to the other requisite components of the composition as recited by the instant claims.

Shiroyama et al teach a cool feeling composition having an excellent cool feeling is obtained by blending at least one cool feeling agent such as p-menthane-3,8-diol with vanillyl butyl ether. The cool feeling composition is capable of imparting a long-



lasting and strong cool feeling when used in cosmetics, toiletries, etc. See Abstract. Suitable toiletry compositions include shampoos, etc. See column 4, lines 15-45. In general, the content of the cool feeling composition ranges from 0.001% to 20% by weight of the whole product composition. See column 4, line 60 to column 5, line 5.

It would have been obvious to one of ordinary skill in the art, at the time the invention was made, to use a cool feeling composition containing p-menthane-3,8-diol with vanillyl butyl ether in the composition taught by Ogino et al, Niemiec et al, or Wetzel, with a reasonable expectation of success, because Shiroyama et al teach that a composition containing p-menthane-3,8-diol with vanillyl butyl ether produces an excellent cold sensation in a similar topical cleaning composition which would be desirable and enhance the sensation provided by menthol as taught in the compositions disclosed by Ogino et al, Niemiec et al, or Wetzel.

### ***Response to Arguments***

With respect to the rejection of the instant claims under 35 USC 103 using Ogino et al, Niemiec et al, or Wetzel, all in view of Watson et al, Applicant states that there is no suggestion in any of the cited prior art references to combine two or more cooling agents. Additionally, Applicant states that not only would it not have been obvious to combine Watson with Ogino et al, Niemiec et al, or Wetzel, but that Watson teaches against such a combination because Watson teaches that menthol has disadvantages such as strong odor and relative volatility. Furthermore, Applicant states that the proposed combination fails to disclose the ratio of component (A) to component (B) as recited by the instant claims. In response, note that, the Examiner maintains that

Watson et al teach that the N-substituted-p-menthane-3-carboxamides provide a cooling sensation, similar to that of menthol, in personal care compositions; essentially, the prior art teaches the equivalence of menthol to N-substituted-p-menthane-3-carboxamides as cooling agents and it is prima facie obvious to combine two compositions, each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose...[T]he idea of combining them flows logically from their having been individually taught in the prior art. In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See MPEP 2144.06.

While Applicant states that Watson teaches away from the use of menthol due to its strong odor and would replace menthol with N-substituted-p-menthane-3-carboxamides, the Examiner maintains that the primary references of Ogino et al, Neimiec et al, or Wetzel teach the use of menthol which is thus a desirable and suitable in component in those compositions. The Examiner maintains that Watson's teaching of the strong odor of menthol and the desire to produce other cooling sensation compounds which do not possess a strong odor does not amount to a negative teaching or a teaching away from using cooling sensation carboxamide compounds in combination with menthol. Watson et al is merely pointing out the fact that menthol has a strong odor, which is a well-known fact, and that other compounds possess the similar cooling effects of menthol without the strong odor. Nowhere is it stated in Watson et al that the disclosed carboxamides could not or should not be used in combination with menthol. In fact, Watson et al specifically states that menthol is still extensively used in

topical, ingestible, and other compositions depending upon the end use which clearly recognizes that menthol is used as a cooling agent (See column 1, line 35 to column 2, line 5). The Examiner maintains that one of ordinary skill in the art would clearly be motivated and have a reasonable expectation of success to use the claimed carboxamide compounds in combination with menthol as taught by Ogino et al, Neimiec et al, or Wetzel as an additional cooling agent which, depending upon the desired end use and application, could mitigate the minty odor or menthol while still providing the same amount of cooling sensation.

Further, with respect to the ratio of component (A) to component (B) as recited by the instant claims, note that, Watson et al teach that the amount of N-substituted-p-menthane-3-carboxamide added to a personal care composition will usually be in the range of 0.5 to 4% by weight based on the total weight of the composition (See column 8, lines 40-60 of Watson et al) and that the teachings of Ogino et al, Neimiec et al, or Wetzel in combination with Watson et al would suggest compositions having a ratio of component (A) to component (B) which would fall within the scope of the instant claims (for example 4:1 ratio). For example, 3.5% by weight of menthol as suggested by Ogino et al and 0.5% by weight of carboxamide as suggested by Watson et al or 3.5% by weight of menthol as suggested by Neimiec et al and 0.5% by weight of carboxamide as suggested by Watson et al would result in a ratio of 7:1 and would fall within the scope of the instant claims. Thus, the Examiner maintains that the teachings of Ogino et al, Neimiec et al, or Wetzel, all in combination with Watson et al suggest the composition as recited by the instant claims.

Also, Applicant states once again that data has been presented in the instant specification which shows the unexpected and superior properties of the claimed invention in comparison to compositions falling outside the scope of the instant claims. Specifically, for example, Applicant states that compositions, as set forth in Table 3, containing a mixture of menthol and N-ethyl-p-menthane-3-carboxamide, provides unexpected and superior cooling and refreshing effect in comparison to compositions containing only menthol or N-ethyl-p-menthane-3-carboxamide. Additionally, Applicant states that the examples provided in the specification discuss precisely what the cited prior art references disclose and that even though an example for each possible compound of claim 1 is not provided, each of the compounds in claim 1 is supported by the specification. Thus, Applicant concludes that the data presented in the specification is commensurate in scope with the instant claims. In response, note that, the Examiner maintains, as stated previously, that the data presented in the instant specification is not sufficient to place the instant claims in condition for allowance. The data presented is not commensurate in scope with the instant claims. For example, as stated previously, the instant claims are open to various cool and refreshing feeling substances (component A), various N-substituted-p-menthane-3-carboxamide compounds, any anionic surfactant, any water-soluble high molecular weight polymer and/or any polyhydric alcohol in broad amounts while the data presented in the instant specification shows results for only embodiments containing menthol, N-ethyl-p-menthane-3-carboxamide, one specific anionic surfactant, and several polymers and/or alcohols in limited amounts which is not commensurate in scope with the instant claims. While

Applicant states that each of the compounds in claim 1 is supported by the specification, the Examiner maintains that support for the claimed subject matter is not the issue at hand but whether the data presented is commensurate in scope with the broad number of compounds and amounts of said compounds as recited by the instant claims. As another example, the instant specification provides data with respect to a composition containing 4% menthol and 1% of the carboxamide compounds which is not commensurate in scope with the ratio of (A) to (B) of 70:30 to 99:1 as recited by the instant claims.

Alternatively, even if the data presented in the instant specification was commensurate in scope with the instant claims, which the Examiner is clearly not conceding, it appears that the data presented in instant specification merely shows what one of ordinary skill in the art would reasonably expect from the teachings of the prior art and is therefore, not unexpected. Note that, as stated previously, Watson et al teaches that the N-substituted-p-menthane-3-carboxamide compounds "provide a pronounced physiological cooling effect, in many cases far more persistent than that obtained with menthol" (See column 2, lines 5-30 of Watson et al) such that one of ordinary skill in the art would reasonably expect results similar to the data presented in the specification when using a combination of menthol and N-ethyl-p-menthane-3-carboxamide. Thus, the Examiner asserts that the data presented in the instant specification is not sufficient to show the unexpected and superior properties of the claimed invention in comparison to compositions falling outside the scope of the instant claims.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Remaining references cited but not relied upon are considered to be cumulative to or less pertinent than those relied upon or discussed above.

Applicant is reminded that any evidence to be presented in accordance with 37 CFR 1.131 or 1.132 should be submitted before final rejection in order to be considered timely.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory R. Del Cotto whose telephone number is (571) 272-1312. The examiner can normally be reached on Mon. thru Fri. from 8:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon can be reached on (571) 272-1498. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Gregory R. Del Cotto/  
Primary Examiner, Art Unit 1796

/G. R. D./  
April 28, 2009